

REMARKS/ARGUMENTS**Claim Objections**

The Examiner objected to Claim 4 because the period was missing from the end. The Applicant has made appropriate correction.

Claim Rejections - 35 U.S.C. 103

The Examiner rejected claims 1, 2, 4-8, 10-14, 16-20 and 22-24 under 35 U.S.C. 103(a) as being unpatentable over Becker et al. (U.S. Patent No. 6,712,757) in view of Kadan (U.S. Patent No. 6,419,654).

The Examiner stated: "In regard to claims 1, 4, 7, 10, 13 and 16, Becker et al. teach a sleeve 10 comprised of a cylinder 22 that received the outer tube of an endoscope 28 (see Figures 1 and 6). A docking member 24 including a cavity 50 to snugly receive the proximal end of the endoscope is mounted at the proximal end of cylinder 22 and has an internal means for communicating with the central bore in cylinder 22 (see Figure 1).

Docking member 24 also includes an annular groove 56 and an O-ring 59 for forming an air and water tight seal between the endoscope and the docking member 24 (see Figure 4). Becker et al. also teach fluid inlet port 12 and suction port 14 that are in communication with the central bore in cylinder 22 for irrigation and suction (see Figure 1). However, fluid inlet port 12 and suction port 14 are positioned on the cylinder 22, not the docking member 24. Kadan discloses a similar lavage system comprised of a handpiece 10 attached to a cannula 22 where handpiece 10 includes irrigation and suctioning channels 26 and 28 that are in communication with an internal means in handpiece 10 for providing irrigation and suction (see Figure 1). Kadan thus demonstrates that providing channels or ports for irrigation and suction on the proximal or handpiece portion of a lavage system is well known in the art. Accordingly, it would have been obvious for one of ordinary skill in the art at the time the invention was made to position the fluid inlet port 12 and suction port 14 of Becker et al. on the docking member 24, in the manner disclosed by Kadan.

In regard to claims 2, 8 and 14, Figure 7 of Becker et al. shows that, as broadly as claimed, the distal end of cylinder 22 is fenestrated. In regard to claims 5, 6, 11, 12, 17 and 18, Figure 1 of Becker et al. shows that docking member 24 comprised a hollow center. Furthermore, the fluid inlet port 12 and suction port 14, as placed in the position contemplated by Becker et al. in view of Kadan (above), would comprise peripheral bores for allowing fluid and suction to access the internal means of docking member 24 and the interior channel of cylinder 22.”

In regard to claims 1, 4, 7, 10, 13 and 16, the Becker et al. invention is intended for cleaning the window of an endoscope and producing a fluid spray for irrigating the body cavity. See Abstract; Figure 7; column 4, lines 46-61; and claim 1. The instant invention is intended for gastrointestinal lavage¹ with subsequent vacuuming of the lavage fluid (see page 15, lines 14-19; and page 10, lines 7-8). Claims 1, 7, 13 and 19 have been amended to make this clear.

Additional support for these amendments can be seen at page 17, line 19 to page 18, line 6.

Also, the Becker et al. invention is rigid (see column 3, lines 10-11) while the instant invention is flexible (see page 17, line 1). All claims except claim 13 reflect that the tube of the instant invention is flexible. Claim 13 has been amended to reflect this feature.

Additionally, the Becker et al. invention has two separate channels attached to the side of the cylinder. See column 3, lines 10-11; and Figures 2, 5 and 7. Fluid goes down one channel and is suctioned up through the other channel. See column 4, lines 46-61. In contrast, in the instant invention there is only one central bore 18 through the tube 14. See page 17, line 19 to page 18, line 6.

The above referenced amendments serve to distinguish the claims of instant invention from the Becker et al. invention.

¹ Lavage means “A washing, especially of a hollow organ such as the stomach or lower bowel, with repeated injections of water.” *The American Heritage® Stedman's Medical Dictionary* Copyright © 2002, 2001, 1995 by Houghton Mifflin Company. Published by Houghton Mifflin Company.

While the Becker et al. and the instant invention are in the same field of medical examination and treatment, namely endoscopy, the Kadan invention is intended for application in the field of arthroscopy. Endoscopy comprises placing an instrument into a body cavity through an existing orifice. Example: examining and treating the stomach through the mouth. Arthroscopy comprises examination and treatment of the interior of a joint using an endoscope that is inserted into the joint through a small incision².

The combination of elements from non-analogous sources, in a manner that reconstructs the applicant's invention only with the benefit of hindsight, is insufficient to present a *prima facie* case of obviousness. There must be some reason, suggestion, or motivation found in the prior art whereby a person of ordinary skill in the field of the invention would make the combination.³

The fact that the classification for the Kadan invention is US 604/27 and the classification of the Becker et al. invention is US 600/121 amply demonstrates that they are in non-analogous fields. An inventor in the field of endoscopy would not look to the field of arthroscopy for solution of his problems.

In regard to claims 2, 8 and 14, Applicant respectfully disagrees that Becker et al. shows any sort of fenestration. Fenestration means an opening in the surface of a structure, as in a membrane. The word comes from the Latin "fenestra", meaning window. All the openings 82 in the instant invention are in the side wall of the tube 14. See Figure 5. A side wall is clearly equivalent to a membrane. Thus they can properly be called fenestrations. Referring to Figure 2 of the Becker et al. invention, element 38 is called a hood. It is at the distal end of the fluid conduit 36. The other opening 32 is the distal end of the suction conduit. Both the openings in the Becker et al. invention are at the ends of tubes. Thus they are not placed in a membrane and cannot be fenestrations.

² *The American Heritage® Stedman's Medical Dictionary Copyright © 2002, 2001, 1995 by Houghton Mifflin Company. Published by Houghton Mifflin Company.*

³ *In re Oetiker*, 977 F.2d 1443, 24 USPQ 2d 1443, 1446 (Fed. Cir. 1992)

The Applicant respectfully traverses the Examiner's rejection of claims 5, 6, 11, 12, 17 and 18. First, claims 5, 11 and 17 make no mention of hollow centers. All of them concern peripheral bores. Simple mention of an element of a claim in a prior art reference does not make that element obvious. The invention must be considered "as a whole"⁴. Claims 6, 12 and 18 are dependent and thus include all the limitations of the claims from which they depend. Therefore, these claims are not made obvious by mention of a hollow center in the Becker et al. patent.

The Examiner stated: "In regard to claims 19, 20 and 22, see the above rejections for claims 1, 2 and 4." In regard to claims 19, 20 and 22 Applicant points to his responses above for claims 1, 2 and 4.

The Examiner stated: "With further respect to claims 19 and 20 and in regard to claims 23 and 24, see col. 6, lines 20-60 of Becker et al. Furthermore, inherent in the device disclosed by Becker et al. is the capability to perform method steps outlined in claims 19, 20, 23 and 24 of the instant invention."

In regard to claims 19, 20, 23 and 24, claim 15 of Becker et al. describes a very different invention. The Becker et al. invention is intended for cleaning the window of an endoscope and producing a fluid spray for irrigating the body cavity. Also, the Becker et al. invention is rigid while the instant invention is flexible. Additionally, the Becker et al. invention has two separate channels attached to the side of the cylinder. Fluid goes down one channel and is suctioned up through the other channel. In contrast, in the instant invention there is only one central bore 18 through the tube 14. All the openings 82 in the instant invention are in the side wall of the tube 14 and thus they can properly be called fenestrations. In contrast, both the openings in the Becker et al. invention are at the ends of tubes. Thus they cannot be fenestrations. See above for more detailed explanation and citations.

For these reasons, applicant respectfully disagrees that the device disclosed by Becker et al. is inherently capable of performing the method steps of claims 19, 20, 23 and 24.

⁴ See 35 U.S.C. 103(a)

The Examiner rejected claims 3, 9, 15 and 21 under 35 U.S.C. 103(a) as being unpatentable over Becker et al. (U.S. Patent No. 6,712,757) in view of Kadan (U.S. Patent No. 6,419,654), as applied above, and further in view of Butler et al. (U.S. Patent Application Publication No. 2002/01 47385). The Examiner stated: "In regard to claims 3, 9, 15 and 21, Becker et al. are silent as to pleats on cylinder 22. However, Butler discloses a similar colonic tube comprised of corrugations 5 on an overtube I for an endoscope so that the overtube I has lateral flexibility (see Figure 1 of Butler). Butler thus demonstrates that corrugations or pleats on a tube that is designed to enter the colon are well known in the art for easing insertion and providing flexibility. Accordingly, it would have been obvious for one of ordinary skill in the art at the time the invention was made to provide the cylinder 22 of Becker et al. with corrugations, in the manner disclosed by Butler, to aid in insertion and provide flexibility."

In regard to claims 3, 9, 15 and 21 Butler et al. relates to tubes for colon scopes while the instant invention relates to tubes for endoscopes. Furthermore the tube of Butler et al. is fully corrugated and intended for maintaining a section of colon in a straightened condition (see Claim 1) while the pleats in the instant invention are only in the medial section and intended to promote flexibility and prevent collapse of the bore (see page 15, lines 18-22).

There is no teaching or suggestion in either Becker et al. or Butler et al. to combine their teachings. Therefore, the combination of Becker et al. with Butler et al will not render the instant invention obvious.

Additional amendments

Applicant noted that there was no antecedent basis for the peripheral bores mentioned in claim 19 c) and d). Applicant replaced all references to "internal means" in claim 19 a) with mention of the peripheral bores. Support for this amendment can be seen in claim 5. No new matter has been added.

Conclusion

The Examiner stated: "The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Applicant should note the following prior art reference disclosing an irrigation/suction sheath for an endoscope: Glowa et al., U.S. Patent No. 6,086,542."

Applicant has noted the prior art made of record and particularly the Glowa et al. reference but does not believe these affect the patentability of his invention.

No extra fee is due on account of this Amendment. Reconsideration of this application and its early allowance are respectfully requested in view of the above presented amendments and remarks.

Respectfully submitted,



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